



Billing Code: 4 162-20 P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities Under Emergency Review by the Office of Management and Budget

The Substance Abuse and Mental Health Services Administration (SAMHSA) has submitted the following request (see below) for emergency OMB review under the Paperwork Reduction Act (44 U.S.C. Chapter 35). OMB approval has been requested by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. A copy of the information collection plans may be obtained by calling the SAMHSA Reports Clearance Officer at (240) 276- 1243.

***Title:* Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner” - NEW**

OMB Number: 0930-New

Frequency: On Going

Affected public: Nurse Practitioners and Physician Assistants

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an emergency Office of Management and Budget (OMB) review and approval of the Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other

Practitioner. The Notification of Intent would allow SAMHSA to determine whether other practitioners are eligible to prescribe certain approved narcotic treatment medications for the maintenance or detoxification treatment of opioid addiction.

This Notification of Intent is a result of the Comprehensive Addiction and Recovery Act (PL 114-198), which was signed into law on July 22, 2016. The law establishes criteria for nurse practitioners (NPs) and physician assistants (PAs) to qualify for a waiver to prescribe covered medications. To be eligible for a waiver, the NP or PA must: be licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain; fulfill qualification requirements in the law for training and experience; and fulfill qualification requirements in the law for appropriate supervision by a qualifying physician. SAMHSA has the responsibility to receive, review, approve, or deny waiver requests.

Practitioners who meet the statutory requirements will be eligible to prescribe only those opioid treatment medications that are controlled in Schedules III, IV, or V, under the Controlled Substance Act (CSA), that are specifically approved by the Food and Drug Administration (FDA) for the treatment of opioid addiction, and are not the subject of an “adverse determination.” The only medications that currently fulfill these requirements are ones that contain the active ingredient buprenorphine.

Given the severity of the opioid epidemic, SAMHSA is requesting an emergency OMB approval. Emergency OMB approval will enable NPs and PAs to dramatically increase access to buprenorphine among individuals with opioid use disorder.

The following table is the estimated hour burden:

Purpose of Submission	Number of Respondents	Responses/Respondent	Burden Hours	Total Burden Hours
Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Nurse Practitioners	816	1	.066	54
Notification of Intent for Qualifying Other Practitioner to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction by a “Qualifying Other Practitioner” under 21 USC § 823(g)(2) – Physician Assistants	590	1	.066	39
Total	1,406	-	-	93

Written comments and recommendations concerning the proposed information collection should be sent by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, OMB. To ensure timely receipt of comments, and to avoid potential delays in OMB’s receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via e-mail to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their

comments via e-mail, commenters may also fax their comments to: 202-395-5806.

Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, D.C. 20503.

Summer King
Statistician

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